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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,641	08/25/2000	Ronda M. Allen	04121.0165-00000	5632
22852	7590	07/18/2005		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/648,641	Applicant(s) ALLEN ET AL.	
	Examiner Michael V. Meller	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10-15,17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims 3-9, 19-26 which are drawn to an invention nonelected with traverse in Paper No. 3.

The election is still proper and remains FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10-15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bezuglyi et al. (abstract), Bernard et al. (title, abstract) or Grandogenett et al. (see whole reference, especially figure 4) taken with Arezi et al. (see whole reference, especially paragraph 28, 34, 36), Hogrefe et al. (see whole reference, especially paragraph 9), Bult et al. (see whole reference, especially col. 25,

Art Unit: 1655

line40-col. 26, line 17), or Hjorleifsdottir et al. (see whole reference, especially col. 19, lines 7-37).

Bezuglyi et al., Bernard et al., or Grandogenett et al. each teach a DNA polymerase being purified using Poly U Sepharose chromatography.

They do not teach specifically to do this with an archaeal polymerase but as shown by Arezi et al., Hogrefe et al., Bult et al., or Hjorleifsdottir et al. these enzymes (archaeal polymerases) are known in the art and are known to be purified.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the archaeal polymerases and cells since such cells and enzymes are well known in the art as is evidenced by Arezi et al., Hogrefe et al., Bult et al., or Hjorleifsdottir et al. and are known to be purified using chromatography.

To purify such enzymes and cells using poly U sepharose is simply the choice of the artisan in an effort to optimize the desired results. Chromatography is a well known step of purification for many protein including enzymes. To use a well known chromatography system such as Poly U Sepahrose to purify a DNA Polymerase is known in the art. Since such enzymes are routinely purified using Poly U Sepharose chromatography, then it had to have been prima facie obvious to use the same chromatography for the same type of enzyme the **only** difference being that the enzyme came from a different source. Thus, when one of ordinary skill in the art was going to purify the archaeal polymerase he would have used the poly u sepharose since it was routinely used to purify DNA polymerases in general. The **only** difference was that the enzyme came from a different source but the enzyme is still a DNA polymerase.

Art Unit: 1655

Applicant argues that different types of chromatography are used for different types of enzymes, but the art is clear that it is well known to purify polymerases using Poly U sepharose chromatography. The art is also clear that archaeal polymerases are well known and well known to be purified. Thus, it is clearly within the purview of the skilled artisan in an effort to optimize the desired results to purify the archaeal polymerases using the Poly U sepharose. Once again, the only difference between the primary references and the invention is that the enzyme source is different but it is the same enzyme, namely a DNA polymerase.

Hogrefe teaches that archaeal polymerases from *Pyrococcus furiosus* are well known and come in two types both of which are known.

Applicant now argues that Lasken (supplied by applicants) teaches that archaeal DNA polymerases bind tightly to uracil-containing DNA which inhibits the polymerases. Then they add, that uracil-containing RNA does not inhibit archaeal polymerases, suggesting that such polymerases do not tightly bind to uracil-containing RNA. Then they add a teaching that Poly U Sepharose comprises uracil-containing RNA coupled to the Sepharose matrix. The only problem with this argument is that Lasken only says that uracil in RNA does not have the same effect as dUrd in DNA (see page 17693, right column, first full paragraph) **not** that that such polymerases do not tightly bind to uracil-containing RNA. Thus, the argument is without merit. This is not a proven fact by applicant. DNA polymerases (as is shown by the art of record) are routinely purified using Poly U Sepharose chromatography.

Applicant next argues that Grandgenett teaches endonuclease activity but the DNA polymerase is still purified using the same Poly U Sepharose as applicants have used.

Next applicants argue that Bezuglyi and Bernard do not teach using the Poly U sepharose to purify archaeal polymerase but this is not a 35 USC 102 rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant continues to argue that archaeobacterial polymerases possess characteristics often not found in their eubacterial, eukaryotic and bacteriophage counterparts, but this does not establish that the combination is not obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1655

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael V. Meller
Primary Examiner
Art Unit 1654

MVM